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IN THE

# Supreme Court of the United States

THE BUCKMAN COMPANY,

*Petitioner,*

v.

PLAINTIFFS' LEGAL COMMITTEE,

*Respondent.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit**

## AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENT

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## AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENT

## IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ("ATLA") respectfully submits this brief as amicus curiae in this case. Letters from Petitioner and Respondent granting blanket consent to the filing of *amicus curiae* briefs have been filed with this Court.[1]

[1] Pursuant to Rule 37.6, Amicus discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than Amicus Curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

ATLA is a voluntary national bar association whose approximately 50,000 trial lawyer members primarily represent individual plaintiffs in civil actions, including actions seeking damages for wrongful death and personal injury, vindication of civil rights protected under federal and state statutes, and in other actions seeking legal redress.

ATLA is concerned that the broad scope of implied preemption sought by Petitioner and supporting *amici* in this case seriously undermines the fundamental right to seek legal redress for wrongful harm. Elimination of state law remedies in the absence of clearly expressed intent by Congress not only diminishes fundamental right of Americans to access to the courts, but undermines the healthy federalism that is the hallmark of our justice system.

## SUMMARY OF THE ARGUMENT

ATLA strongly disagrees with the position advanced by the United States as Amicus Curiae that plaintiffs' cause of action is impliedly preempted by federal law.

I. The intent of Congress remains the ultimate touchstone of preemption analysis, including assertions of implied preemption. The Solicitor General argues that permitting plaintiffs to recover damages for the harm caused by violation of that duty under state law presents a "fatal conflict" with the federal regulatory scheme. In short, the Solicitor General's position is that federal law does not preempt the state law duties or requirements on which plaintiffs base their claims, but impliedly preempts state remedies for their violation.

In ATLA's view, the Solicitor General overstates the duty not to deceive federal agencies as among the unique federal interests that require the displacement of state law. Although federal agencies undoubtedly have a strong interest in the truthfulness and reliability of the information



submitted to them, this is not a uniquely national interest. By basing preemption of state law on any federal interest that can be characterized as important, the Solicitor General treats the intent of Congress, as reflected in the provisions of the statute, as inessential.

At the same time, the Solicitor General undervalues the interests of the states in affording legal redress for physical injury caused by tortious misconduct. The fraud cause of action alleged by plaintiffs tracks the well-settled tort of liability for physical harm caused by intentional misrepresentation to a third party. Although the third party in this instance is the FDA, misrepresentation to a governmental agency is not an essential element of the tort.

Moreover, the interest protected by this common law tort is not the interest of the third party not to be deceived. It is the interest of those who foreseeably may be physically harmed as a result of the misrepresentation. The protection of health and safety by awarding damages for harm caused by tortious conduct is an area that has traditionally been occupied by state law.

II. The Solicitor General argues that three types of conflict with the federal regulatory scheme result from allowing plaintiffs' state law cause of action for physical injury resulting from misrepresentations to the FDA: That state remedies undermine the FDA's exclusive authority in enforcing requirements for truthful disclosures, that they conflict with FDA's decision to grant market clearance, and that they may impose on the FDA burdensome entanglements in private litigation.

ATLA submits that none of these concerns present a significant conflict with Congress's purposes and objectives as reflected in the express provisions of the MDA. Indeed, the statutory provisions reflect a regime in which state remedies supplement federal enforcement. The absence of a federal private cause of action argues in favor of the

preservation of state remedies. The speculative burden on the FDA may support steps to ensure the agency's efficient operation, but does not support interference with the states' authority within our system of federalism to provide legal redress for wrongful injury to its citizens.

## ARGUMENT

### I. PLAINTIFFS' STATE TORT ACTION FOR PERSONAL INJURIES RESULTING FROM FRAUD OR MISREPRESENTATION DOES NOT INTRUDE ON UNIQUELY NATIONAL INTERESTS, BUT PROTECTS HEALTH AND SAFETY, A FIELD TRADITIONALLY OCCUPIED BY STATE LAW.

Plaintiffs in this case are people who suffered physical harm allegedly caused by pedicle screws used in spinal surgical procedures. They allege that they were exposed to this danger as a result of defendant's conscious misrepresentations to the Food and Drug Administration in obtaining approval to market the devices.

The lower courts have not yet ruled that plaintiffs' claim states a valid cause of action under state law or that plaintiffs' evidence is sufficient on each of the essential elements. *See* 159 F.3d 817, 829 (3d Cir. 1998). For this reason, ATLA views much of Petitioner's discussion of the appropriate interpretation of the company's representations of "intended use" as not directly responsive to the limited Question Presented.

ATLA agrees with the position stated in the Brief of the United States as Amicus Curiae that plaintiffs' state law cause of action is not expressly preempted by the Medical Device Amendments of 1967 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). The Solicitor General correctly states that plaintiffs' "common law theory of liability does not rest on the imposition of a duty that is



'different from' or 'in addition to' federal requirements. Instead, that common law theory is consistent with the duties imposed by applicable federal requirements." [U.S. Br. at 19-20]

ATLA, however, strongly disagrees with Part II of the Brief of the United States, which argues that permitting plaintiffs to recover damages for the harm caused by violation of that duty under state law presents a "fatal conflict" with the federal regulatory scheme. In short, the Solicitor General's position is that federal law does not preempt the state law duties or requirements on which plaintiffs base their claims, but impliedly preempts state remedies for their violation.

In ATLA's view, the Solicitor General overstates the duty not to deceive federal agencies as among the "unique federal interests that require the displacement of state law." U.S. Br. at 23. At the same time, the Solicitor General undervalues the interests of the states in affording legal redress for physical injury caused by tortious misconduct. The protection of health and safety by awarding damages for harm caused by tortious conduct is an area that has traditionally been occupied by state law.

#### A. Remedies for Harms Resulting from Misrepresentation to Federal Agencies Are Not A Matter of Such Uniquely National Concern that Congress May Be Presumed to Intend Preemption.

The intent of Congress remains "the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). It is no less essential in implied preemption cases, where the Court has recognized three bases for superseding state law.

> If Congress has not entirely displaced state regulation over the matter in question, state law is still pre-empted to the extent it actually conflicts with federal

> law, that is, when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.

*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984). Regardless of the type of implied preemption asserted, the "ultimate question in each case, as we have framed the inquiry, is one of Congress's intent, as revealed by the text, structure, purposes, and subject matter of the statutes involved." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545 (1992) (Scalia, J. dissenting).

In instances of "field" preemption and "impossibility" preemption, congressional intent to supersede conflicting state law can reasonably be inferred. However, this is not a case in which Congress has made clear its intent to preempt the entire field of regulation, leaving no room for state law to supplement it. *Cf. United States v. Locke*, 120 S. Ct. 1135 (2000). Indeed, the Court in Medtronic held that the Medical Device Amendments expressly provide for a role for state regulation and state causes of action for compensation. Nor is compliance with state and federal duties not to deceive impossible, since they are consistent. [U.S. Br. at 19-20]

Rather, the Solicitor General asserts, permitting the state law damages remedy sought by plaintiffs raises the possibility of a conflict with federal interests.

*Hines v. Davidowitz*, 312 U.S. 52 (1941), established the principle of implied preemption of state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." This Court held that Pennsylvania's Alien Registration Act must yield in the face of uniquely national interest. Justice Black emphasized that "it is of importance that this legislation is in a field which affects international relations, the one aspect of our government that from the first has been most generally conceded imperatively to demand broad national authority.



Any concurrent state power that may exist is restricted to the narrowest of limits." 312 U.S. at 67-68.

Implicit in *Hines* is the notion that the fact that a state law intrudes in a field that is intrinsically national, and in which the states powers are necessarily limited, can serve as a proxy for congressional intent that the state law must yield. As the Court later explained, in a case involving local regulation of blood plasma:

> [I]n the seminal case of *Hines v. Davidowitz*, [312 U.S. 52 (1941)], the Court inferred an intent to preempt from the dominance of the federal interest in foreign affairs because 'the supremacy of the national power in the general field of foreign affairs . . . is made clear by the Constitution,' . . . and the regulation of that field is intimately blended and intertwined with responsibilities of national government. Needless to say, those factors are absent here. Rather, as we have stated, the regulation of health and safety matters is primarily and historically, a matter of local concern.

*Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985)

Curiously, the Solicitor General does not cite *Hines*, instead relying most heavily on *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988). In that case, plaintiff sought recovery for wrongful death against the manufacturer of a military helicopter which crashed. The Court determined that plaintiff's state product liability claim would impose a duty that conflicted with the requirements in defendant's contract with the United States government. The Court therefore held that state law was trumped by a federal government contractor defense fashioned by the Court, in the absence of a statutory provision, as a matter of federal common law.

Extending *Boyle's* judicial preemption to this case, where Congress has provided a regulatory statute -- which includes an express preemption provision -- makes the intent of Congress, as reflected in the text and purposes of the statute, nonessential.

The Solicitor General would extend the breadth of this new preemption even further. The Court in *Boyle* repeatedly emphasized that the scope of its decision was narrow, limited it to situations in which there is a "significant conflict" between state law and matters of "uniquely national interest." *Id.* at 507. The Solicitor General quickly casts aside that limiting principle in favor of interests that may be important to federal agencies, but are not uniquely national.

Undoubtedly, it is important that agencies receive accurate and truthful information from regulated entities. But deceit is not uniquely national. Moreover, given the myriad activities requiring federal approvals or licenses, the impact of misrepresentation extends far beyond the federal government. For example, if a company fraudulently procures a patent which it uses to entice investors, those who suffer losses are in no different position than the victims of misrepresentations made to a state agency or private party. *Cf. Belmac Hygiene, Inc. v. Belmac Corp.*, 121 F.3d 835 (2d Cir. 1997)(under Florida law, defendant could be liable to corporate investor based on partner's misrepresentation to FDA concerning the testing of a contraceptive which defendant used to persuade plaintiff to invest in the venture.)

Federal law, of course, must govern the reporting and disclosure obligations of entities regulated by federal agencies. However, where state law imposes no different or additional duty, no "significant conflict" with uniquely national interests arises from permitting a compensatory remedy. As the plurality stated in *Cipollone*, there is "no general, inherent conflict between federal preemption of state



warning *requirements* and the continued vitality of state common law damages actions," 505 U.S. at 518.

Even in a field of such overriding national interest as safety regulation of nuclear power, this Court found no inconsistency between "vest[ing] the NRC with exclusive regulatory authority over the safety aspects of nuclear development while at the same time allowing plaintiffs like Mr. Silkwood to recover for injuries caused by nuclear hazards." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984). On this point, the dissent agreed. "Compensatory damages therefore complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme." *Id.* at 264 (Blackmun, J., dissenting).

Cut loose from its anchor in the intent of Congress, the theory of preemption proposed by the Solicitor General "invites an unelected federal judiciary to make decisions about which state policies it favors and which ones it dislikes." *Garcia v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528, 546 (1985). In doing so it tramples on important principles of federalism.

**B. The Cause of Action for Physical Harm Resulting From Misrepresentation Is A Traditional Tort Within the Historic Role of the States.**

This Court in *Medtronic* reaffirmed the strong presumption against preemption when Congress legislates in a field that state law has traditionally occupied, particularly in matters affecting health and safety. 518 U.S. at 485. Acknowledging this longstanding principle, U.S. Br. at 17, the Solicitor General would nonetheless cast it aside in this instance.

The Solicitor General takes the position that plaintiffs' is not a traditional product liability claim, but rather a "newly fashioned state-law tort of committing fraud on a federal regulatory agency." U.S. Br. at 18. Consequently, the Solicitor General argues, plaintiffs' cause

of action is not within an area traditionally occupied by the states and would not even exist but for the federal statute involved. It is an area governed entirely by federal law concerning the relationship between federal agencies and regulated entities, where the states have no legitimate role. *Id.*

The Solicitor General insists upon characterizing this tort as "fraud on the FDA" as if the federal agency were an essential element of the tort. Count I in Plaintiffs' sample complaint is entitled "Fraud (on the FDA)." The parentheses clearly distinguish this allegation of fraud accomplished by intentional misrepresentation to a third party (here the FDA), from alleged misrepresentations made directly to doctors and patients.

The Solicitor General misunderstands the nature and history of this cause of action. From at least the end of the 18th Century, common law courts imposed liability on one who makes an intentional misrepresentation to a third party, inducing justifiable reliance which results in harm to the plaintiff. 2 Fowler V. Harper, Fleming James, Jr., and Oscar S. Gray, THE LAW OF TORTS § 7.1 (2d ed. 1986). Liability extended to one who makes misrepresentations contained in documents required by statute to be filed with a government agency. *Id.* at § 7.2; Restatement of Torts (Second) § 536 (1977).

This basis of liability was reflected in Restatement (First) of Torts § 310 (1938), and was incorporated, with some change in wording, in Restatement (Second) of Torts §310 (1965). That section provides:

> An actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by ... a third person in reliance upon the truth of the representation, if the actor
> (a) intends his statement to induce or should realize that it is likely to induce action by ... a third person, which involves an unreasonable risk of physical harm to the other, and
> (b) knows
> (i) that the statement is false, or
> (ii) that he has not the knowledge which he professes.



It is most important to note that, although the misrepresentation is made to a third party, the tort does not exist to protect that party's interest in not being deceived. Rather, "liability is based upon the unreasonable risk of physical harm which is involved in the misrepresentations, and not upon the fact that the misrepresentations are intended to mislead." *Id.* comment a.

There are relatively few reported cases applying section 310 to liability for product related injuries for the obvious reason that it is generally far easier to establish strict liability and misrepresentation under 402A and 402B. For this reason, the dire warnings of massive liability that would follow upon a ruling against preemption are suspect.

## II. PLAINTIFFS' STATE LAW REMEDIES FOR FRAUD BASED ON MISREPRESENTATIONS TO THE FDA PRESENT NO SIGNIFICANT CONFLICT WITH THE FEDERAL REGULATORY SCHEME.

The Court in *Boyle* emphasized that a unique federal interest is a necessary, but not sufficient basis for displacing state law. There must also be a "significant conflict" with federal law. 487 U.S. at 507-08. The Solicitor General suggests three bases for eliminating plaintiffs' state law cause of action for physical injury resulting from misrepresentations to the FDA: state remedies undermine the FDA's exclusive authority in enforcing requirements for truthful disclosures; they conflict with FDA's decision to

grant market clearance; and they may impose on the FDA burdensome entanglements in private litigation.

ATLA submits that none of these concerns present a significant conflict with Congress's purposes and objectives as reflected in the express provisions of the MDA. Indeed, the statutory provisions reflect a regime in which state remedies supplement federal enforcement. The absence of a federal private cause of action argues in favor of the preservation of state remedies. The speculative burden on the FDA may support steps to ensure the agency's efficient operation, but does not support interference with the states' authority to provide legal redress for wrongful injury to their citizens.

In sum, the arguments represent an example of "seeking out conflicts between state and federal regulation where none clearly exists." *English v. General Electric Co.*, 496 U.S. 72, 81, 90 (1990), quoting *Huron Portland Cement Co. v. City of Detroit*, 362 U.S. 440, 446 (1960)

**A. Congress's Regulatory Scheme Does Not Require Exclusive FDA Control To the Exclusion of State Remedies to Compensate the Victims of Fraud or Misrepresentation**

*1. The Express Provisions of the Medical Device Amendments Establish A Regime In Which State Remedies Supplement FDA Enforcement.*

The Solicitor General's primary argument in favor of denying plaintiffs the right to seek compensation under state law is that, even when state law does not impose different or additional *requirements,* permitting a compensatory *remedy* outside the agency's control conflicts with the FDA's exclusive authority to determine whether it has been defrauded and what penalty, if any to exact. U.S. Br. at 21.

This Court in *Medtronic* discerned no such conflict:



> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. . . . The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

518 U.S. at 495.

The dissenting Justices were of the same view:

> Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id. at 513 (O'Connor, J., dissenting in part).

Although the Court's primary focus in *Medtronic* was the MDA's express preemption provision, it is surely unlikely that a conflict of the significance described by the Solicitor General would have escaped all notice.

Moreover, the enforcement provisions which Congress adopted in the MDA do not exclude state remedies, but clearly establish a regime in which FDA enforcement and state remedies are supplementary.

For example, 21 U.S.C. § 360g makes provision for judicial review of the variety of regulations and orders (or the modification or revocation of regulations or orders) issued under sections 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k. Congress explicitly provided in Section 360g(e): "The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law."

Even more instructive is the regime Congress has established in § 360h for enforcement of orders to repair or replace unreasonably dangerous devices and reimburse the patient or buyer for all the expenses actually incurred.

As originally proposed, the section vested sole discretion for making these determinations and ordering the appropriate remedies in the FDA. In testimony before the Senate Subcommittee on Health of the Committee on Labor and Public Welfare, representatives of the device and pharmaceutical makers voiced their concerns with the provision as drafted. They were particularly concerned with the allocation of exclusive authority to the FDA, to the exclusion of state product liability court actions where they had enjoyed success in defending their products.

Foster Whitlock, vice-chairman of Johnson & Johnson's board of directors and chairman of the Pharmaceutical Manufacturers Association, stated that S. 2368 § 515(c) (the original draft of §360h) "will result in a substantial and significant change in the traditional legal approach to the handling of product liability matters. . . This provision does not provide the manufacturer with a hearing before the determination is made to require these remedies. Nor does it expressly give the manufacturer a choice of remedies." Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, U.S. Senate, 93rd Cong., 1st Sess. pp. 463-64 (1975).

Kenneth A. Marshall, representing the Health Industries Association, stated that "Replacement or



reimbursement are matters which should not be left to the secretary . . . the question of whether a product is defective is ultimately decided by a jury." *Id.* at 477.

C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association, testified:

> We agree that manufacturers should be liable for defective products as is the case under the law today. The provision would result in a substantial and significant change in the traditional legal approach to the handling of product liability matters. It could eventually replace the current court-adjudication system in liability in individual cases with an administrative class-action approach.

*Id.* at 362.

In response to these concerns, Congress modified § 360h in a number of respects. Provision was made for consultation and informal hearings with manufacturers. Most significantly, Congress added § 360h(d) to make clear that it was not eliminating common law product liability actions. That section provides:

(d) Effect on other liability

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Congress not only contemplated that state damage lawsuits would continue after enactment of the MDA, but it took pains to address any potential conflict with FDA enforcement by harmonizing the recoverable damages to

avoid double recovery by plaintiffs. *See also Mulligan v. Pfizer,* 850 F. Supp. 633, 636 (S.D. Ohio 1994)(holding that § 360h(d) reflects congressional intent to preserve state tort claims).

*2. Preemption of State Remedies Would Undermine Purposes and Objectives of Congress.*

By definition, misrepresentation and fraud are intended to deceive the FDA. To rely solely on the FDA to determine whether it has been defrauded and impose the only sanction would appear to be an extraordinary vote of confidence in the power and ability of the agency to police a very large industry without any additional assistance from the states.

In reality, state law product liability lawsuits have made an important contribution to achieving Congress's purpose of ensuring the safety of medical devices marketed to the public. Nowhere has this contribution been more important than in those instances where companies have been guilty of misrepresentation or failure to disclose serious dangers in medical devices. One need look no further than the experience with the Dalkon Shield, a device which inflicted harm on thousands of women, prompting a large number of lawsuits and providing the impetus for passage of the MDA itself. *Medtronic,* 518 U.S. at 476 The story does not support the Solicitor General's insistance that proper regulation of the device industry demands reliance solely on FDA enforcement without the "hindrance" of product liability lawsuits. U.S. Br. at 18.

> Robins' dishonesty regarding the efficacy of its device, its refusal to conduct adequate testing of the Dalkon Shield, its ignoring of numerous adverse reports from physicians, its attacks on the personal character of victims in product liability lawsuits, and, ultimately, its suppression and illegal destruction of damning evidence against it were uncovered only after years of product liability litigation, some of which was unsuccessful because of Robins' suppression of critical evidence. In fact, none of this evidence was sought by, or discovered, by FDA. To the contrary, FDA turned its attention away from the Dalkon Shield after negotiating a "voluntary" suspension of sales in the United States on June 26, 1974. Not until 1984, ten years later, after being publicly castigated by a federal judge overseeing a group of product liability cases, did Robins finally begin a campaign to convince women to have the IUDs removed.



Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 944-45 (1994). The authors conclude that "had preemption been applied to the Dalkon Shield, A.H. Robins would have succeeded in operating incompetently and illegally. More importantly, hundreds of thousands of injured women would have been denied recompense and justice. . . . despite its commendable efforts on behalf of the public, FDA simply cannot provide an adequate source of safety to the public from dangerous medical devices. *Id.* at 945 *See generally*, Richard B. Sobol, Bending the Law: THE STORY OF THE DALKON SHIELD BANKRUPTCY, 2-48 (1991).

In fact, Congress has repeatedly identified shortcomings in FDA's regulation of medical devices. *See, e.g.,* Subcommittee on Oversight and Investigations, House Committee on Energy & Commerce, *Less Than the Sum of its Parts: Reforms Needed in the Organization, Management, and Resources of the FDA's Center for Devices and Radiological Health*, 103d Cong., 1st Sess. (Comm. Print 103-N, May 1993); Staff of House Committee on Energy & Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn,"* 101 Cong., 2d Sess. (Comm. Print 101-R, 1990); *see*

*also* U.S. General Accounting Office, *Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting* (1986); U.S. General Accounting Office, Comptroller General, *Federal Regulation of Medical Devices: Problems Still To Be Overcome* (1993).

In sum, the plain language of the Medical Device Amendments demonstrates that Congress intended to preempt different or additional state *requirements*, but intended to preserve state *remedies*. To require that enforcement depend solely upon the sanctions imposed by the FDA, to the exclusion of state law damage remedies for victims, would undermine the objective and purpose of Congress in enacting the MDA.

**B. Permitting Plaintiffs' State Law Remedy Is Not Inconsistent With Congress's Decision Not to Provide a Private Federal Cause of Action.**

The district court ruled that plaintiff's Count I claim is preempted, reasoning that to allow plaintiffs to pursue their damages remedy under state law conflicts with Congress's decision not to create a private cause of action for damages caused by violation of the Federal Food Drug and Cosmetic Act and the Medical Device Amendments. See 159 F.3d at 825. The Third Circuit reversed, correctly stating that the district court's ruling was "contrary to the clear holding of *Lohr*." *Id.*

Nevertheless, the Solicitor General argues that the absence of a private cause of action is part of a comprehensive regulatory scheme in which the FDA must have "exclusive authority to determine how the provisions of the Act should be enforced." U.S. Br. at 22-23. The Pharmaceutical Research and Manufacturers of America echo this position: "Congress's decision not to create a federal private right of action to enforce the FFDCA and MDA does



not suggest that injured parties should be permitted to seek compensation under *state* law." PRMA Br. at 14.

To the contrary, this Court has long held that state damage remedies are not impliedly preempted where those harmed by tortious conduct would be left without any remedy. As this Court stated in *United Construction Workers v. Laburnum Const. Co.*, 347 U.S. 656, 663-64 (1954).

> Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct. For us to cut off the injured respondent from this right of recovery will deprive it of its property without recourse or compensation. To do so will, in effect, grant petitioners immunity from liability for their tortious conduct. We see no substantial reason for reaching such a result.

Again, in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), the Court refused to deprive injured plaintiffs of state law remedies in the absence of an explicit statement that Congress so intended:

> This silence (of Congress) takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

464 U.S. at 251. Justice Blackmun, dissenting in *Silkwood*, nonetheless agreed with the majority that the absence of federal regulation governing the compensation of victims is strong evidence that Congress intended the matter to be left to the States. *Id.* at 264 n.7.

The Court in *Lohr* found this reasoning directly applicable to Medtronic's assertion of preemption under the Medical Device Amendments. In view of the absence of a

private cause of action for damages, the plurality stated, broad preemption of state remedies would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation . . . It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.'" quoting *Silkwood, supra.*

Indeed, Congress has not been entirely silent with respect to its intent in not providing a private cause of action.

As originally drafted, the FDCA in 1938 included section 25, entitled "Liability for Personal Injuries -- a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act." See H.R. 6110, 73rd Cong., 1st Sess. §25 (1933).

Section 25 of the House proposal, which was section 24 of the Senate version, was "striken from the bill on the ground that it is unnecessary. A common-law right of action exists." Hearings on S. 1944 Before a Subcommittee of the Committee on Commerce, U.S. Senate, 73rd Cong., 2d Sess. 400 (1933). *See also id.* at 431 ("the party injured now has every reasonable protection under the law and a right of action for damages."); *id.* at 403 ("This act should not attempt to modify or restate the common law with respect to personal injuries").

Based on this legislative history, courts have concluded that Congress intended that personal injury actions continue to be available under state tort law. *See Consumer Federation of America v. Upjohn,* 346 A.2d 725, 731 (D.C. App. 1975); *Broward County v. Eli Lilly & Co.*, 329 FS 364, 365 (SD Fla. 1971).

**C. Plaintiffs' State Law Damages Remedy Does Not Conflict With FDA Market Clearance Decisions.**



The Solicitor General's second basis for seeking implied conflict preemption is that plaintiffs' lawsuit would impose liability for marketing a device that the FDA has expressly approved for marketing, thereby failing to give effect to the FDA's administrative decision. U.S. Br. at 25-26. The Pharmaceutical Manufacturers echo this point, arguing that permitting injured plaintiffs to seek compensation would allow states "through the imposition of massive civil liability, to effectively override the FDA's approval decision."

What the Solicitor General postulates is a false conflict: A situation where plaintiff alleges defendant violated truthful disclosure requirements, but the FDA has decided to grant (or continue) market clearance anyway. Under the very terms of the Solicitor General's hypothetical situation, the defendant cannot be liable under state law because its statement was not the proximate cause of the FDA's decision. Perhaps the agency did not view the statement as false, or did not deem it material, or for some other reason decided that the drug or device should gain access to the market. In any event, the terms of the hypothetical itself negates an essential element of state law liability, that the FDA would not have granted market access but for the defendant's alleged misrepresentation.

In the case before this Court, there is even less of a basis for finding a clear federal-state conflict. At this stage of the proceeding, it is unknown whether plaintiffs have stated a valid cause of action under state law. The Third Circuit took care to state, "We do not hold that plaintiffs have or have not alleged a legally sufficient causal nexus." 159 F.3d at 827. ATLA suggests that the States should not be presumed in advance to violate their obligations under the Supremacy Clause. The Solicitor General's assertion that any state law cause of action will necessarily fail to give effect to the FDA's administrative decision is purely speculative and premature.

ATLA is most concerned that the Solicitor General seeks a blanket preemption that extends beyond the situation where the FDA stands by its market clearance decision to cases where the agency has condemned a company's fraud, ordered the drug or device withdrawn from the market, and imposed punishment on the company and individuals responsible.

That is precisely the situation that was presented in *Talbott v. Bard*, 865 F. Supp. 37 (D. Mass. 1994), aff'd, 63 F.3d 25 (1st Cir. 1995), cert. denied, 116 S. Ct. 1892 (1996). The manufacturer had obtained market clearance under § 510k by fraudulent statements that failed to disclose known failures caused by a life-threatening defect in the catheter. In the wake of a growing number of deaths and injuries, the FDA opened an inquiry. Ultimately, the investigation resulted in C.R. Bard pleading guilty to 391 counts of conspiracy, mail fraud, lying to regulators, and shipping adulterated products. The company was fined $61 million. Three Bard executives convicted of making false statements to the FDA and were sentenced to eighteen months in prison. *See* Kenneth J. Witzel, Comment, Medtronic, Inc. v. Lohr *and the Power of Preemption: A Pennsylvania Guide To the Preemption of Common Law Tort Claims by the Medical Device Amendments of 1976*, 102 Dick. L. Rev. 865, 880-83 (1998); and Mitchell Zuckoff & John H. Kennedy, "Heart Catheter Became Killer: Mass.-Made Unit Blamed in Fraud," *Boston Globe*, Oct. 31, 1993, at 1.

In a wrongful death suit by the family of one victim, the First Circuit held that the claims were barred by the MDA, employing a broad theory of blanket preemption that this Court subsequently rejected in *Medtronic*. With respect to the company's fraudulent statements made to obtain market approval, the court of appeals ruled that permitting the family to recover damages would conflict with the broad authority of the FDA to order the product off the market and initiate criminal prosecutions. The Pharmaceutical



Manufacturers recognize that the broad implied preemption sought in this case would resurrect *Talbott's* broad immunity from liability. PRMA Br. at 13 n.6.

The United States filed a brief as *amicus curiae* in *Talbott*. The Solicitor General explicitly rejected the rationale that the FDA, not a judge or jury, must be accorded exclusive authority to fix the consequences of a company's fraudulent statements:

> The concern raised in Judge Aldrich's opinion is irrelevant to this case. The FDA initially approve the catheter model that allegedly caused Ms. Beavers' death, but on the basis of "allegedly fraudulent, misleading and inaccurate documentation submitted by Bard," J.A. 287-87. The FDA subsequently initiated enforcement actions against Bard and the other defendants. Thus, to the extent that plaintiffs' state-law claims are premised on the FDA's judgment that Bard failed to comply with federal requirements, there is no risk that additional requirements will be imposed in this case by a judge or jury.

Talbott v. Baird, *supra*, Brief for the United States As Amicus Curiae at 25.

ATLA suggests that the Solicitor General "got it right" in *Talbott*, and that the opposite position the Solicitor General now adopts is inconsistent both with the provisions of the statute and its purposes and objectives.

**D. Speculative Concerns that State Law Damage Actions Will Result in Undesirable Practical Consequences for the FDA Do Not Warrant Their Preemption.**

Finally, the Solicitor General asserts that preemption is necessary to keep the FDA from being burdened and entangled by private lawsuits seeking discovery. U.S. Br. at 28-30.

It does not appear that direct proof of the state of mind of FDA officials is at all necessary to plaintiffs' cause of action. For example, in *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 F.2d 553, 568-69 (3d Cir. 1983) the court held that a patient alleging injury caused by defendant's misleading statements to the FDA produced sufficient evidence of reliance of the part of the FDA through expert testimony.

In any event, as the Solicitor General acknowledges, federal agencies are capable of protecting themselves against overwhelming demands on their personnel made by private parties in litigation. *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951). The Solicitor General complains that some lower courts have taken divergent views concerning the protection of agency personnel. U.S. Br. at 28-29. The Solicitor General's argument is properly addressed to the reviewing authority of this Court. It does not compel eliminating state causes of action on the ground that they may generate more subpoena requests.

Further, courts are authorized to protect nonparties from overly burdensome discovery. Fed. R. Civ. Pro. 26 and 45. Congress, of course, possesses ample authority to provide sufficient resources to federal agencies and to protect them from inappropriate drain on those resources.

As for the speculation that potential liability may prompt regulated entities to submit more information than the FDA desires, U.S. Br. at 30, the Supremacy Clause does not represent a blanket authorization for federal agencies to enlist the assistance of state courts to accomplish their missions.

This Court had recent occasion to recall the explanation by Chief Justice Marshall that the federal government's "means are adequate to its ends; and on those means alone was it expected to rely for the accomplishment of its ends." *McCulloch v. Maryland*, 4 Wheat. 316, 424 (1819), quoted in *Alden v. Maine*, 527 U.S. 706, 753 (1999)



The Court further cautioned, "When Congress legislates in matters affecting the States, it may not treat these sovereign entities as mere prefectures or corporations," but must treat them as "joint participants in the federal system." *Id.* at 758.

## CONCLUSION

For the above reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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